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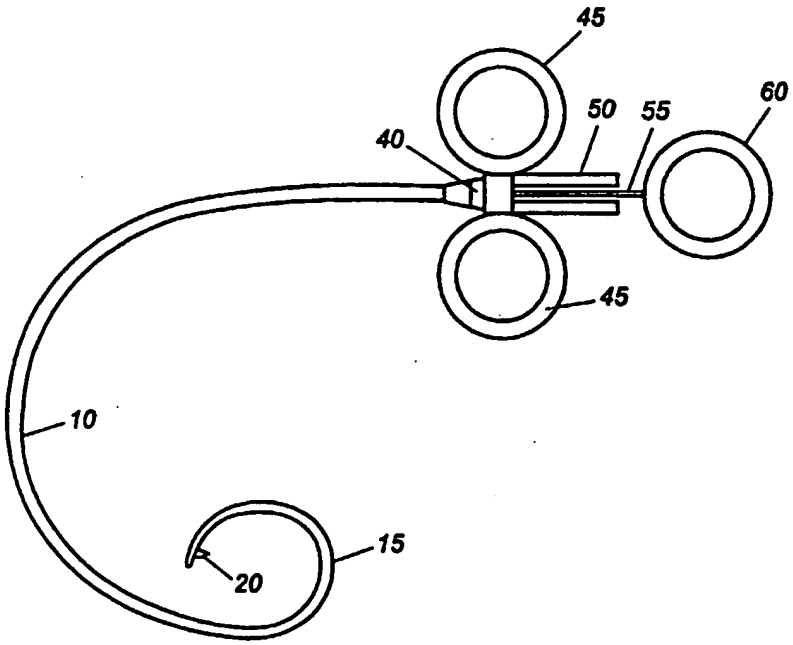
(54) Title: TRABECULOTOMY DEVICE AND METHOD FOR TREATING GLAUCOMA

(57) Abstract

Surgical catheter devices and methods for decompressing elevated intraocular pressure in eyes affected by glaucoma by performing a selected trabeculotomy from within Schlemm's canal.



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TRABECULOTOMY DEVICE AND METHOD FOR TREATING GLAUCOMA

Cross - Reference to Related Applications

This application claims the benefit of U.S. Provisional Application No. 60/131,030, filed April 26, 1999.

Technical Field

The present invention is generally directed to a surgical treatment for glaucoma, and relates more particularly to a device and method for continuously draining aqueous fluid and decompressing elevated intraocular pressure in eyes affected by glaucoma by performing a trabeculotomy by incising the trabecular meshwork with a bladed device threaded within the circumference of Schlemm's canal.

Background of the Invention

Glaucoma is a significant public health problem, because glaucoma is a major cause of blindness. The blindness that results from glaucoma involves both central and peripheral vision and has a major impact on an individual's ability to lead an independent life.

Glaucoma is an optic neuropathy (a disorder of the optic nerve) that usually occurs in the setting of an elevated intraocular pressure. The pressure within the eye increases and this is associated with changes in the appearance ("cupping") and function ("blind spots" in the visual field) of the optic nerve. If the pressure remains high enough for a long enough period of time, total vision loss occurs. High pressure develops in an eye because of an internal fluid imbalance.

The eye is a hollow structure that contains a clear fluid called "aqueous humor." Aqueous humor is formed in the posterior chamber of the eye by the ciliary body at a rate of about 2.5 microliters per minute. The fluid, which is made at a fairly constant rate, then passes around the lens, through the pupillary opening in the iris and into the anterior chamber of the eye. Once in the anterior chamber, the fluid drains out of the eye through two different routes. In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for ten percent of the aqueous outflow. The primary pathway for aqueous outflow is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal.

The trabecular meshwork and Schlemm's canal are located at the junction between the iris and the sclera. This junction or corner is called "the angle." The trabecular meshwork is a wedge-shaped structure that runs around the circumference of the eye. It is composed of collagen beams arranged in a three-dimensional sieve-like structure. The beams are lined with a monolayer of cells called trabecular cells. The spaces between the collagen beams are filled with an extracellular substance that is produced by the trabecular cells. These cells also produce enzymes that degrade the extracellular material. Schlemm's canal is adjacent to the

trabecular meshwork. The outer wall of the trabecular meshwork coincides with the inner wall of Schlemm's canal. Schlemm's canal is a tube-like structure that runs around the circumference of the cornea. In human adults, Schlemm's Canal is believed to be divided by septa into a series of autonomous, dead-end canals.

The aqueous fluid travels through the spaces between the trabecular beams, across the inner wall of Schlemm's canal into the canal, through a series of collecting channels that drain from Schlemm's canal and into the episcleral venous system. In a normal situation, aqueous production is equal to aqueous outflow and intraocular pressure remains fairly constant in the 15 to 21 mm Hg range. In glaucoma, the resistance through the canalicular outflow system is abnormally high.

In primary open angle glaucoma, which is the most common form of glaucoma, the abnormal resistance is believed to be along the outer aspect of trabecular meshwork and the inner wall of Schlemm's canal. It is believed that an abnormal metabolism of the trabecular cells leads to an excessive build up of extracellular materials or a build up of abnormally "stiff" materials in this area. Primary open angle glaucoma accounts for approximately eighty-five percent of all glaucoma. Other forms of glaucoma (such as angle closure glaucoma and secondary glaucomas) also involve decreased outflow through the canalicular pathway but the increased resistance is from other causes such as mechanical blockage, inflammatory debris, cellular blockage, etc.

With the increased resistance, the aqueous fluid builds up because it cannot exit fast enough. As the fluid builds up, the intraocular pressure (IOP) within the eye increases. The increased IOP may

compromise the vascular supply to the optic nerve that carries vision from the eye to the brain. Some optic nerves seem more susceptible to IOP than other eyes. While research is investigating ways to protect the nerve from an elevated pressure, the only therapeutic approach currently available in glaucoma is to reduce the intraocular pressure.

The clinical treatment of glaucoma is approached in a step-wise fashion. Medication often is the first treatment option. Administered either topically or orally, these medications work to either reduce aqueous production or they act to increase outflow. Currently available medications have many serious side effects including: congestive heart failure, respiratory distress, hypertension, depression, renal stones, aplastic anemia, sexual dysfunction and death. Compliance with medication is a major problem, with estimates that over half of glaucoma patients do not follow their correct dosing schedules.

When medication fails to adequately reduce the pressure, laser trabeculoplasty often is performed. In laser trabeculoplasty, thermal energy from a laser is applied to a number of noncontiguous spots in the trabecular meshwork. It is believed that the laser energy stimulates the metabolism of the trabecular cells in some way, and changes the extracellular material in the trabecular meshwork. In approximately eighty percent of patients, aqueous outflow is enhanced and IOP decreases. However, the effect often is not long lasting and fifty percent of patients develop an elevated pressure within five years. The laser surgery is not usually repeatable. In addition, laser trabeculoplasty is not an effective treatment for primary open angle glaucoma in patients less than fifty years of age, nor is it effective for angle closure glaucoma and many secondary glaucomas.

If laser trabeculoplasty does not reduce the pressure enough, then filtering surgery is performed. With filtering surgery, a hole is made in the sclera and angle region. This hole allows the aqueous fluid to leave the eye through an alternate route.

The most commonly performed filtering procedure is a trabeculectomy. In a trabeculectomy, a posterior incision is made in the conjunctiva, the transparent tissue that covers the sclera. The conjunctiva is rolled forward, exposing the sclera at the limbus. A partial thickness scleral flap is made and dissected half-thickness into the cornea. The anterior chamber is entered beneath the scleral flap and a section of deep sclera and trabecular meshwork is excised. The scleral flap is loosely sewn back into place. The conjunctival incision is tightly closed. Post-operatively, the aqueous fluid passes through the hole, beneath the scleral flap and collects in an elevated space beneath the conjunctiva. The fluid then is either absorbed through blood vessels in the conjunctiva or traverses across the conjunctiva into the tear film.

Trabeculectomy is associated with many problems. Fibroblasts that are present in the episclera proliferate and migrate and can scar down the scleral flap. Failure from scarring may occur, particularly in children and young adults. Of eyes that have an initially successful trabeculectomy, eighty percent will fail from scarring within three to five years after surgery. To minimize fibrosis, surgeons now are applying antifibrotic agents such as mitomycin C (MMC) and 5-fluorouracil (5-FU) to the scleral flap at the time of surgery. The use of these agents has increased the success rate of trabeculectomy but also has increased the prevalence of hypotony. Hypotony is a problem that develops when aqueous flows out of the eye too fast. The eye pressure

drops too low (usually less than 6.0 mmHg); the structure of the eye collapses and vision decreases.

Trabeculectomy creates a pathway for aqueous fluid to escape to the surface of the eye. At the same time, it creates a pathway for bacteria that normally live on the surface of the eye and eyelids to get into the eye. If this happens, endophthalmitis may develop. Endophthalmitis can occur anytime after trabeculectomy. The risk increases with the thin blebs that develop after MMC and 5-FU. Another factor that contributes to infection is the placement of a bleb. Eyes that have trabeculectomy performed inferiorly have about five times the risk of eye infection than eyes that have a superior bleb. Therefore, initial trabeculectomy is performed superiorly under the eyelid, in either the nasal or temporal quadrant.

In addition to scarring, hypotony and infection, there are other complications of trabeculectomy. The bleb can tear and lead to profound hypotony. The bleb can be irritating and can disrupt the normal tear film, leading to blurred vision. Patients with blebs generally cannot wear contact lenses. All of the complications from trabeculectomy stem from the fact that fluid is being diverted from inside the eye to the external surface of the eye.

Many of the preceding complications of current trabecular surgery would be reduced or eliminated by a technology that shunted aqueous fluid into Schlemm's canal and avoided external drainage. A controlled incision of the entire circumference of the trabecular meshwork through a single, small puncture access would achieve this goal.

A method of performing an incision of intravascular areas of stenosis is disclosed by U.S. Patent No. 5,053,044. The '044 reference teaches the use of a vascular catheter containing a controllable, pivoted blade at its distal tip. A vascular catheter, such as the one disclosed by the '044 reference, is generally placed under radiographic control, so that the area of incision can be confined to the specific zone of the stenosis. The requisite scale of vascular catheters is also much larger than the much smaller scale needed for ophthalmic applications, leaving much of the mechanical options used in vascular applications unavailable in the fabrication of instruments sized to fit within Schlemm's canal. Moreover, the nature of vascular stenosis tends to involve concentric lesions which do not require incision in any particular orientation, whereas an incision into the trabecular meshwork from within Schlemm's canal must be made in a precise vector to avoid collateral injuries to other structures of the eye.

U.S. Patents Nos. 5,472,440 and 5,312,394 are directed to an apparatus and method for performing a filtering operation for glaucoma, both utilizing a jig to guide an oscillating blade and a fiberoptic laser assembly. Both the '440 and the '394 provide a laser-guided dissection of the sclera, with the laser producing a hole through the choroid layer to allow egress of vitreous to decompress the globe. The jig disclosed by both the '440 and '394 patents is mechanically complex, and the method taught by those patents involves relatively extensive external incisions to achieve a reduction in the intraocular pressure. Both of these patents involve external drainage of aqueous fluid.

Surgeons now perform trabeculotomies using metal probes within Schlemm's canal, but this technique has numerous complications

and can only open a small portion of Schlemm's canal. Other researchers have performed a 360° trabeculotomy in children with a prolene suture threaded through Schlemm's canal. However, this procedure has not been reported for the treatment of adult glaucoma because Schlemm's canal was not believed to be patent in adults.

There is a need, therefore, for a less invasive procedure than traditional trabeculectomy with decreased risk of postoperative scarring. Furthermore, there is a need for a complete surgical treatment that allows aqueous humor fluid direct access to Schlemm's canal.

Summary of the Invention

The present invention is directed to a novel surgical device and an associated method for the surgical treatment of glaucoma in which the device is threaded in a specific orientation into some or all of the circumference of Schlemm's canal, and the device is then employed to make a longitudinal incision from within Schlemm's canal into the trabecular meshwork, either at specific points along the canal or continuously as the device is withdrawn from the canal. The present invention therefore facilitates the normal physiologic pathway for drainage of aqueous humor from the anterior chamber.

Brief Description of the Drawings

FIG. 1 is an illustration showing a side view of one embodiment of the present invention, in which the inventive surgical device comprises a catheter with an operable pivoting blade controlled mechanically by the motion of a control wire within the catheter lumen.

FIG. 2 is a detail of the terminal aspect of the embodiment of the present invention in FIG 1, showing the relationships among the control wire, the catheter, and the pivoting blade.

FIG. 3 is an illustration showing another embodiment of the present invention in which the inventive surgical device comprises a dual lumen inflatable catheter in which a distended balloon element causes a pivoting blade to extend.

FIG. 4 is a detail of the terminal aspect of the embodiment of the present invention in FIG 3, showing the relationships among the catheter, the balloon element, and the pivoting blade.

FIG. 5A is an illustration showing another possible embodiment of the inventive device comprises a single lumen inflatable catheter in which a distended balloon element causes a pivoting blade to extend.

FIG. 5B is a detail of the terminal aspect of the embodiment of the present invention in FIG 5A, showing the relationships among the catheter, the balloon element, and the pivoting blade with the balloon fully collapsed for insertion into Schlemm's canal.

FIG. 5C is a detail of the terminal aspect of the embodiment of the present invention in FIG 5A, showing the relationships among the catheter, the balloon element, and the pivoting blade with the balloon fully distended for incision of Schlemm's canal.

FIG. 6 is an illustration showing the relevant anatomic details of the human eye.

Detailed Description of Present Invention

The present invention provides a surgical catheter device to perform a trabeculotomy within a selected portion of Schlemm's canal of the human eye. The device comprises a proximal portion manually controllable by a user, and a distal portion shaped and sized to be received circumferentially within a portion of Schlemm's canal. The distal portion is equipped with a blade that can be extended to incise the wall of Schlemm's canal facing the trabecular meshwork. The blade can be retracted, or remain extended while the device is withdrawn from a portion of the canal, leaving a continuous incision through the wall of Sclemm's canal towards the trabecular meshwork as the distal portion traverses a selected region of the circumference of the canal. Therefore, the blade on the distal portion of the catheter device is movable between a first insertion position and a second incising position when manually actuated via the proximal portion. An actuating lumen extending from the proximal portion to the distal portion places the proximal and distal portions in communication.

The proximal portion of the catheter device, in conjunction with the actuating lume and the proximal portion, are designed for the manual control of distal blade actuation, i.e. extension and retraction. The blade actuation may be achieved by an inflatable balloon adjacent a blunt edge of the pivotally attached blade, as described below. The blade actuation may also be achieved by a pivoting mechanism operated by a control wire, also described below. Many alternative actuating

mechanisms known to those in the art of catheters can be provided to extend the blade into an incising position, and to retract the blade.

The present invention also provides surgical catheter devices for the dilatation of Schlemm's canal of the eye by mechanically distending a portion of the canal when inflated. The catheter devices may also be used to provide a conduit capable of delivering therapeutic and/or expansive medicaments injected therethrough into Schlemm's canal. The surgical catheter devices may also be used to provide a delivery mechanism for stents, shunts and the like into Schlemm's canal to maintain patency within the canal to facilitate the natural drainage of aqueous humor. The device can also comprise a guiding lumen extending from the proximal portion to the distal portion, wherein the guiding lumen contains a steerable guidewire for directing the catheter device into a desired length of Schlemm's canal. Furthermore, optical fibers, cameras, temperature sensors, pressure sensors, and any other probe or suitable useful device can be delivered to within Schlemm's canal by the present invention.

Traditional glaucoma teaching states that Schlemm's canal in an adult is divided by septa into separate canals, rendering the complete passage of a suture impossible. Preliminary studies on adult human eye bank eyes have shown that Schlemm's canal is, indeed, patent. A suture can be passed through the entire circumference of the canal. Therefore, it has not been heretofore determined that Schlemm's canal is patent throughout its circumference in normal adult individuals, as opposed to being divided by septa into multiple dead end canals. The invention utilizes this knowledge to access Schlemm's canal to increase aqueous

humor egress from the anterior chamber to the canal with the present devices.

The present invention is directed to devices and surgical methods for performing a trabeculotomy from within Schlemm's canal. The portion of the device extending circumferentially into Schlemm's canal may be fashioned from a flexible, biologically inert material. The distal portion of the catheter device has a diameter approximately equal to that of Schlemm's canal of a human eye. The diameter of the distal portion can be between about 0.1 and 0.5 mm, or preferably about 0.3 mm. The distal portion of the catheter device can have a pre-formed curve having a radius approximately equal to that of Schlemm's canal. The radius of the distal portion can be between about 3 and 10 mm, or preferably about 6 mm. The length of the distal portion can be between about 1 and 40 mm.

One embodiment of the present invention is illustrated in **FIG. 1** , in which the device comprises a catheter with a proximal end and a distal end. Mechanical hand control by a surgeon at the proximal end is used to control the extension of an operable blade **20** which is pivotally mounted near the distal end. Stationary finger rings **45** are mounted to a central hub **40** which is continuous with the proximal end of a catheter **10**. An extension of the hub **50** contains a lumen that is also continuous with the lumen of the catheter **10**. A control wire **55** extends throughout the catheter **10** and is connected to, and operated by a movable thumb ring **60**, which moves with respect to the stationary finger rings **45** by extension of the thumb of a surgeon's hand, while the stationary finger rings **45** are stabilized by the index and middle fingers of the same hand. The distal end of the catheter **15** is tapered and

preformed in an arcuate configuration, sized to be received within Schlemm's canal. The terminal end of the distal end of the catheter **15** is blunted.

As further detailed in FIG. **2**, a slot **65** is defined on the inner aspect of the arcuate distal end of the catheter **15**. Within slot **65**, a blade **20** is pivotally attached by a pivot pin **25** which is mounted near the proximal end of the slot **65**. The blade **20** contains a blunt, arc-shaped edge **21** which is opposed by a sharpened cutting edge **22**. The control wire **55** extends through the catheter **15**, and is terminally attached to a pin **30** on the surface of blade **20** near its blunted edge **21**. The course and angle of interaction of the control wire **55** is determined within the catheter **15** by guide pins **35** that are positioned to allow for rotation and extension of the blade **20** through slot **65** upon motion of the guide wire **55**.

An alternate embodiment of the present invention is illustrated in FIGS. **3-4**, in which the inventive device comprises a dual lumen catheter comprising a proximal end containing one or more connector ports **3** which allow access to continuous lumens which extend the length of the device. Access to the connector ports **5** may be achieved using a syringe for insufflation with fluids or gases, or by mechanical devices, such as a guide wire **1**, which may be inserted through a port **5** and extend the full length of the device. The catheter shown in this embodiment of the present invention further comprises a distal end of the catheter **15**, which is tapered and preformed in an arcuate configuration, sized to be received within Schlemm's canal. The terminal end of the distal end of the catheter **15** is blunted.

As further detailed in FIG. **4**, a slot **65** is defined on the inner aspect of the arcuate distal end of the catheter **15**. Within slot **65**, a blade **20** is pivotally attached by a pivot pin **25** which is mounted near the proximal end of the slot **65**. The blade **20** contains a blunt, arc-shaped edge **21** which is opposed by a sharpened cutting edge **22**. Immediately distal to the slot **65**, the catheter **15** contains an inflatable balloon element **70**. Rotation and extension of the blade **20** is effected by inflation and distension of the balloon **70**. As the balloon **70** inflates, pressure on the blunted edge **21** of the blade **20** causes the blade **20** to extend and rotate about its pivot point **25**. Subsequent withdrawal of the device with the balloon **70** inflated will result in an incision along Schlemm's canal at the site of its contact with the cutting edge **22** of the blade **20**. In the embodiment of the present invention shown in FIGS. **3-4**, a separate lumen within the catheter is defined by internal tubular walls **75**, and this lumen provides for placement of a guidewire **1** therethrough.

In yet another embodiment of the present invention, shown in FIGS. **5A-5C**, the inventive device comprises a single lumen catheter further comprising a proximal end containing a connector port **3** which allows access to a continuous lumen which extends the length of the device. Access to the connector port **5** may be achieved using a syringe for insufflation with fluids or gases, or by mechanical devices, such as a guide wire **1**, which may be inserted through the port **5** and extend the full length of the device. The catheter shown in this embodiment of the present invention further comprises a distal end of the catheter **15**, which is tapered and preformed in an arcuate configuration, sized to be received within Schlemm's canal. The terminal end of the distal end of the catheter **15** is blunted.

As further detailed in FIG. 4, a slot **65** is defined on the inner aspect of the arcuate distal end of the catheter **15**. Within slot **65**, a blade **20** is pivotally attached by a pivot pin **25** which is mounted near the proximal end of the slot **65**. The blade **20** contains a blunt, arc-shaped edge **21** which is opposed by a sharpened cutting edge **22**. Immediately distal to the slot **65**, the catheter **15** contains an inflatable balloon element **70**. Rotation and extension of the blade **20** is effected by inflation and distension of the balloon **70**. The balloon element **70** may be configureed to expand circumferentially, or its expansion zone may be defined by a predetermined area of elasticity. As the balloon **70** inflates, pressure on the blunted edge **21** of the blade **20** causes the blade **20** to extend and rotate about its pivot point **25**. Subsequent withdrawal of the device with the balloon **70** inflated will result in an incision along Schlemm's canal at the site of its contact with the cutting edge **22** of the blade **20**.

In the embodiment of the present invention as shown in FIGS. **1-5C**, the present invention is directed to devices and surgical methods for incising and enlarging Schlemm's canal utilizing a device that is surgically inserted within at least a portion of Schlemm's canal. The portion of the device extending circumferentially into Schlemm's canal may be fashioned from a flexible, biologically inert material. The distal portion of the catheter device has a diameter approximately equal to that of Schlemm's canal of a human eye. The diameter of the distal portion can be between about 0.1 and 0.5 mm, or preferably about 0.3 mm. The distal portion of the catheter device can have a pre-formed curve having a radius approximately equal to that of Schlemm's canal. The preformed curve is advantageous, as the plane defined by the curve determines the plane of surgical placement of the attached blade, and thus governs the plane of subsequent incisions made by the device. The radius

of the distal portion can be between about 3 and 10 mm, or preferably about 6 mm. In the exemplary embodiment of the present invention, the distal portion **15** is constructed of a biologically inert, flexible material such as silicone or similar polymers. Alternate materials might include, but are not limited to, thin-walled Teflon, polypropylene, or other polymers or plastics.

The surgical anatomy relevant to the present invention is illustrated in FIG. **6**. Generally, FIG. **6** shows the anterior chamber **35**, Schlemm's canal **30**, the iris **40**, cornea **45**, trabecular meshwork **50**, collecting channels **55**, episcleral veins **60**, pupil **65**, and lens **70**. It should be noted that the inventive device is designed so that placement of the distal portion **25** within Schlemm's canal **30** results in an orientation of the extended blade **20** towards the wall of Schlemm's canal **30** adjacent the trabecular meshwork **50**.

The surgical procedure necessary to operate the device requires an approach through a fornix-based conjunctival flap. A partial thickness scleral flap is then created and dissected half-thickness into clear cornea. A radial incision is made at the limbus beneath the scleral flap and deepened until Schlemm's canal is identified and entered posteriorly. The distal portion of the surgical device is grasped and threaded into Schlemm's canal. Once the distal portion of the device is suitably positioned within Schlemm's canal, the blade is extended, and the device is withdrawn with the blade in extension, incising the traversed length of Schlemm's canal. The blade is manually retracted by the proximal portion, and the catheter device is removed from Schlemm's canal. The scleral flap and conjunctival wound are closed in a conventional manner.

While the above-described embodiments are exemplary, the invention contemplates a wide variety of shapes and configurations of the catheter device to effect a suitable trabeculotomy to provide fluid communication between the anterior chamber and Schlemm's canal. The above-described embodiments are therefore not intended to be limiting to the scope of the claims and equivalents thereof.

CLAIMS

What is claimed is:

1. A surgical catheter device to perform a trabeculotomy from within Schlemm's canal of the eye, comprising a proximal portion manually controllable by a user, a distal portion shaped and sized to be received circumferentially within a portion of Schlemm's canal and having a blade thereon, and a blade actuating lumen in communication with and extending from the proximal portion to the distal portion, wherein the blade is movable between a first insertion position and a second incising position when manually actuated via the proximal portion.

2. The catheter device of Claim 1, wherein the distal portion has a diameter of about 0.1 to 0.5 mm.

3. The catheter device of Claim 1, wherein the distal portion has a diameter of about 0.3 mm.

4. The catheter device of Claim 1, wherein the distal portion has a length of about 1.0 to 40.0 mm.

5. The catheter device of Claim 1, wherein the distal portion has a pre-formed curvature having a radius which approximates the radius of Schlemm's canal of a human eye.

6. The catheter device of Claim 1, wherein the distal portion has a pre-formed curvature having a radius of between about 3 mm and 10 mm.

7. The catheter device of Claim 1, wherein the distal portion has a pre-formed curvature having a radius of about 6 mm.

8. The catheter device of Claim 1, wherein the blade is actuated by inflation of the distal portion of the actuating lumen from the proximal portion.

9. The catheter device of Claim 1, wherein the blade is actuated by moving a control wire within the actuating lumen from the proximal portion.

10. The catheter device of Claim 1, further comprising a guiding lumen extending from the proximal portion to the distal portion, wherein the guiding lumen contains a steerable guidewire for directing the catheter device into a desired length of Schlemm's canal.

11. The device of Claim 1, further comprising a medicament delivery lumen extending from the proximal portion to the distal portion, wherein the medicament delivery lumen has at least one fenestration therein on the distal portion for the delivery of medicaments into Schlemm's canal.

12. A method for the surgical treatment of glaucoma and other diseases, comprising inserting the catheter device of Claim 1 into Schlemm's canal and actuating the blade into the incising position.

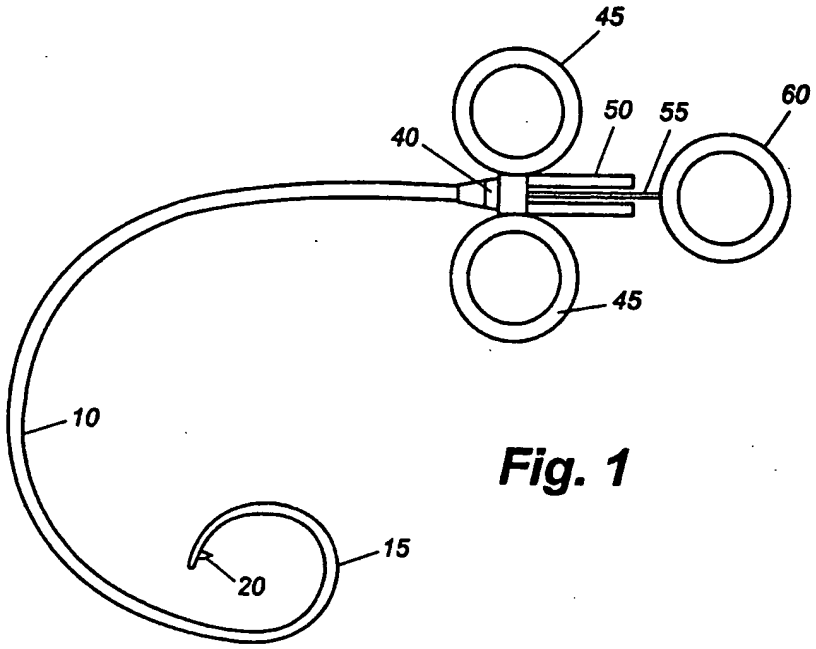

Fig. 1

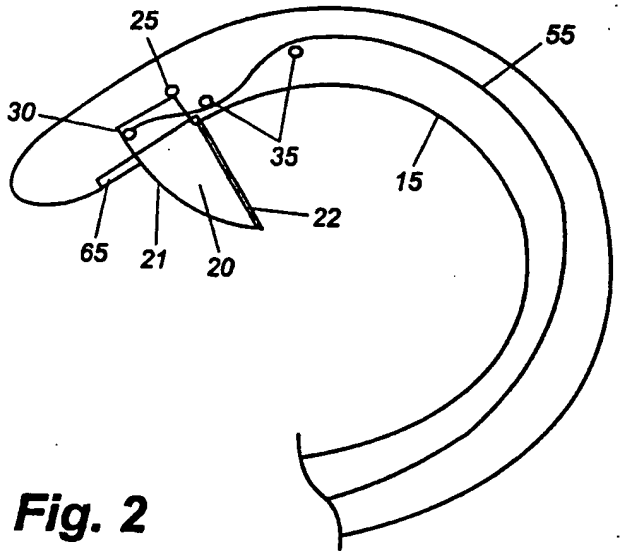

Fig. 2

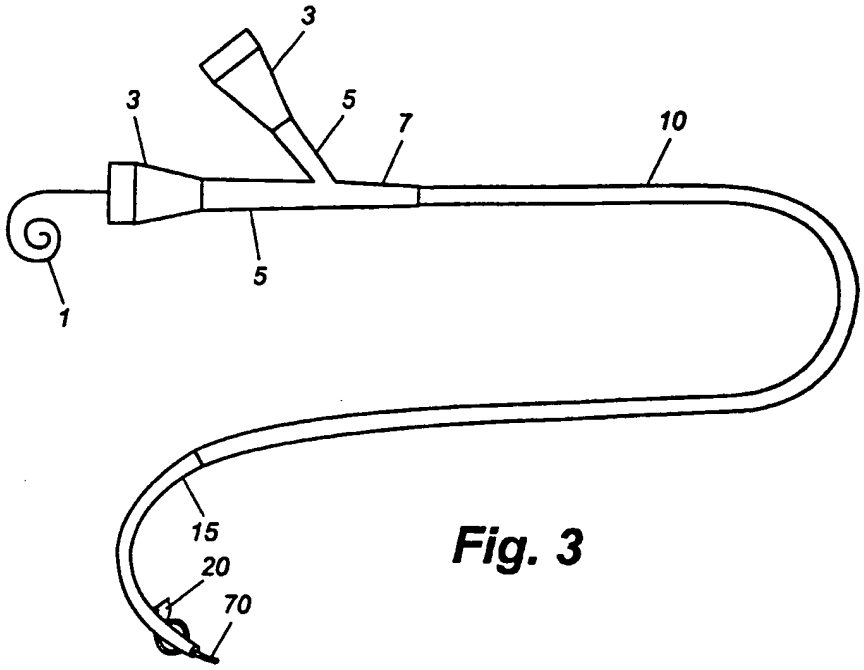

Fig. 3

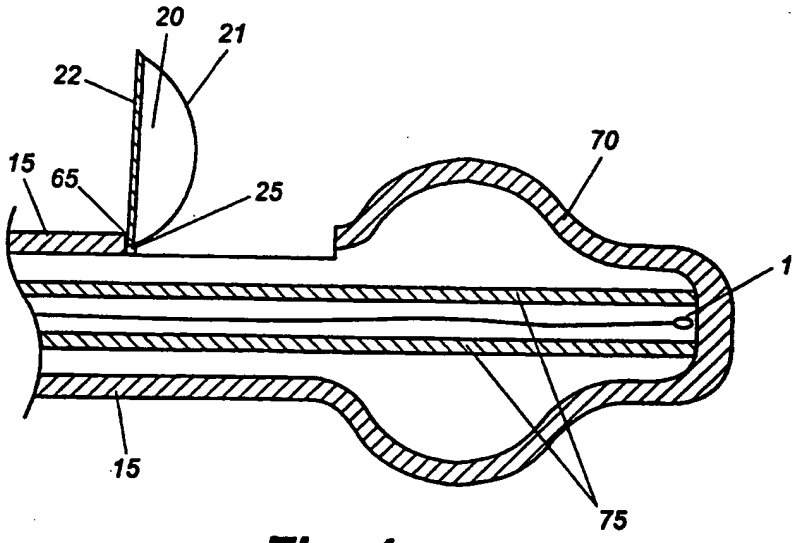

Fig. 4

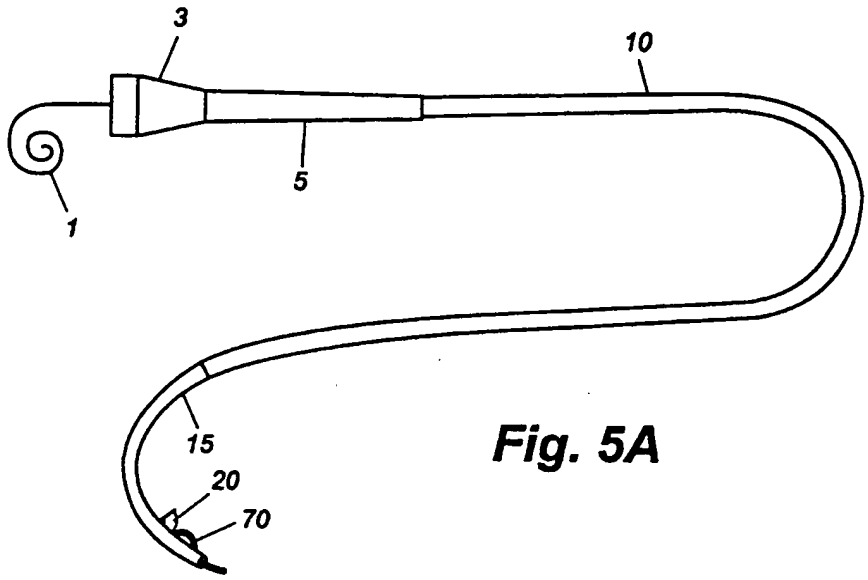

Fig. 5A

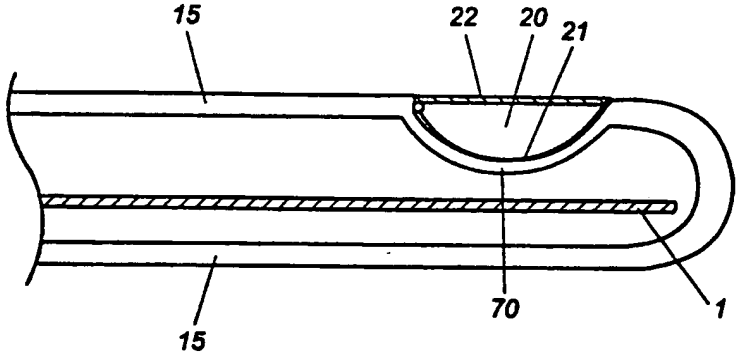

Fig. 5B

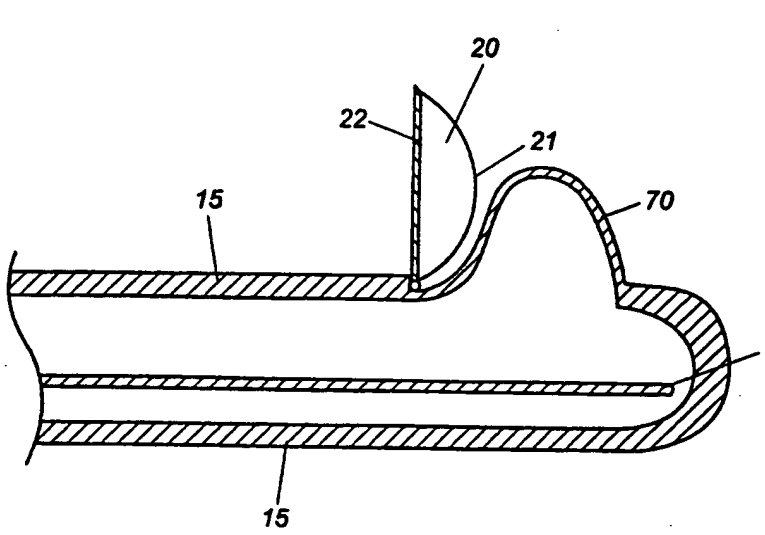

Fig. 5C

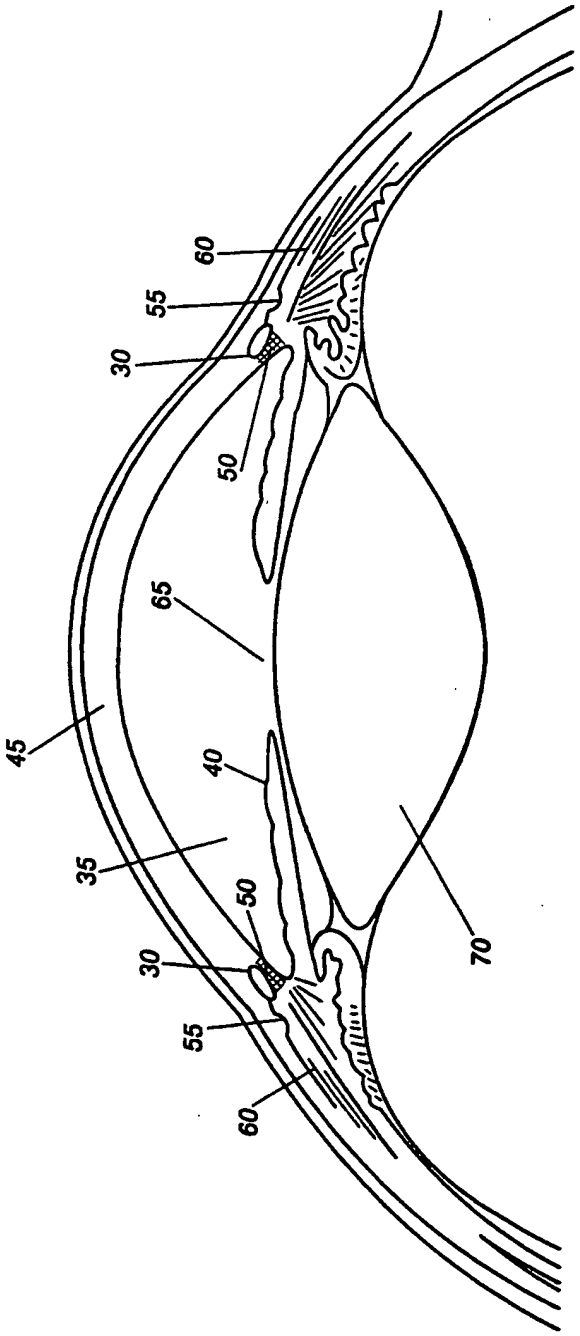

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US 00/11131

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 364 374 A (MOORE CHESTER G ET AL) 15 November 1994 (1994-11-15) column 3, line 11 -column 4, line 14 claims 1-11	1-5
Y		11
A		6-10

Y	US 4 501 274 A (SKJAERPE FINN) 26 February 1985 (1985-02-26) figures 1-4,6 column 3, line 4 - line 54 column 4, line 5 - line 15 claims 1-5,8-11	11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 September 2000	05/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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INTERNATIONAL SEARCH REPORT

Internation. .pplication No
PCT/US 00/11131

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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